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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,165	07/21/2006	Paul B Savage	0179689010-US00	5240
23510 7590 07/20/2007 MICHAEL BEST & FRIEDRICH, LLP ONE SOUTH PINCKNEY STREET P O BOX 1806 MADISON, WI 53701			EXAMINER KRISHNAN, GANAPATHY	
			ART UNIT 1623	PAPER NUMBER
			MAIL DATE 07/20/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/550,165	Applicant(s) SAVAGE ET AL.	
	Examiner Ganapathy Krishnan	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 14-17 and 20-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 18, 19, 24 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/06; 5/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election with traverse of Group I, claims 1-13 and 24-25 in the reply filed on 5/9/2007 is acknowledged. The traversal is on the ground(s) that the relationship between Groups I-IV is that described in 37 CFR 1.475(b) (2), i.e., a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn to a product and process of use. In the instant application the compound of formula I is the product and Groups II-IV are drawn to a process of use of the product of formula I. This is not found persuasive because:

According to 37 CFR 1.475 (c), if an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

According to 37 CFR 1.475 (d), if multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims. See PCT Article 17(3)(a) and § 1.476(c).

Therefore, claims 1-13 and 24-25 in Group I drawn to the compound of formula I, method of making and pharmaceutical compositions comprising compounds of formula I and its first method of use in a method of stimulating NKT cells in Group III, claims 18-19, are considered the main invention.

The inventions listed as Groups II (In the Restriction mailed 4/12/2007, there was a typographical error in Group II. It should have been claims 14-17) and IV do not relate to a

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single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the inventions of Group II and IV are separate and distinct each from the other. Group II is drawn to a probe, which is a product claim and Group IV is drawn to a method stimulating NKT cells.

They have different modes of operation and different functions.

Each group relates to a separate and distinct area of pharmaceutical technology. The search for all inventions would place an undue burden on the examiner in view of the diversity of the inventions and the corresponding diversity in the field of search for each.

Thus, a single general inventive concept is not seen to be present. The requirement is still deemed proper and is therefore made FINAL.

This application contains claims 14-17 and 20-23 drawn to an invention nonelected with traverse in the reply filed on 5/9/2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

Foreign language references listed in the Information Disclosure Statement, for which no English translation has been provided, have not been considered. If an English abstract has been provided for a foreign language document then only the English abstract has been considered.

Specification

The abstract of the disclosure is objected to because: The first page of the WIPO document filed 9/20/2005, which has an abstract, has also been used as the abstract sheet in the instant specification. This is not acceptable if the instant claims are determined to be allowable at a later stage. The Office requires the abstract to be typed on a separate sheet of paper even though applicants intend using the abstract on the WIPO document for the instant application. Hence, applicants are requested to kindly type the abstract appearing on the first page of the WIPO document (WO 2004/094444) on a separate sheet and file the same.

. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-2, 5 and 18-19 are rejected under 35 U.S.C. 102(a) as being anticipated by Savage et al (Organic Letters, 2002, 4(8), 1267-70; document AD in the IDS of 3/3/2006).

Savage et al teach compounds #2 (page 1268, Scheme 1) which meets the limitations of instant formula (I) of claims 1 and 2 for R1-R7 = Hydrogen, R8 = $-(CH_2)_xCH_3$ wherein x is 24 and R9 is linear C3-C10 alkyl group.

Formula 8 of Savage (page 1269, Scheme 2) meets the limitations of instant claim 5.

Savage et al teach the stimulation of NKT cells via contact of the compound of formula I with CD1d (page 1269 right column, paragraph starting above figure 3 through page 1270, line 6). This teaching meets the limitations of instant claims 18-19.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-13, 18-19 and 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Savage et al (Organic Letters, 2002, 4(8), 1267-70; document AD in the IDS of 3/3/2006) in view of Kawano et al (Science, 1997, 278, 1626-29); document cited in IDS of 5/25/2007).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Savage et al teach compounds #2 (page 1268, Scheme 1) which meets the limitations of instant formula (I) for R1-R7 = Hydrogen, R8 = $-(CH_2)_xCH_3$ wherein x is 24 and R9 is linear C3-C10 alkyl group. Savage also teaches compound of formula 8 and 13 (page 1269, Scheme 2 and Figure 2) having a dansyl group and a biotinyl group attached to the carbohydrate moiety via a linker. According to Savage, the galactosyl ceramides of their invention are potent stimulators of human T cells and stimulation occurs through binding of the glycolipids by CD1d, presentation to T cells, and formation of a CD1d-glycolipid-T cell receptor complex (page 1267, abstract; page 1268, right column, second full paragraph). Savage et al teach the stimulation of NKT cells via contact of the compound of formula I with CD1d (page 1269 right column, paragraph starting above figure 3 through page 1270, line 6).

Savage teaches the process for the preparation of compound of formula 10, wherein compound of formula 7 having an azide group is first converted to compound of formula 2, having the amino group at the 6 position of the carbohydrate. Compound 2 is then converted to compound 10 via reaction with compound 9 comprising the N-phthalimido ester linkage (as instantly claimed, group LG in instant claim 24). However, Savage exemplifies only a few

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compounds and their ability to stimulate NKT cells.

Kawano et al, drawn to activation of NKT cells, teach that fatty acyl chains in combination with galactosyl moiety (GalCer) are important for selective activation of NKT cells and it is these cells that kill target tumor cells by an NK like mechanism and inhibit tumor growth and metastasis (page 1628, left column, last paragraph and middle column, first full paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the compounds of formula I, their compositions and use them in a method to stimulate NKT cells and make the said compounds via the process as instantly claimed since such is seen to be taught in the prior art.

One of skill in the art would be motivated to make the compounds and their compositions as instantly claimed since closely analogous compound have been shown to be good stimulators of NKT cells, which are known to inhibit tumor growth and metastasis. Hence one of skill in the art would look for structurally related compounds that are more potent inhibitors.

Conclusion

Claims 1-13, 18-19 and 24-25 are rejected.

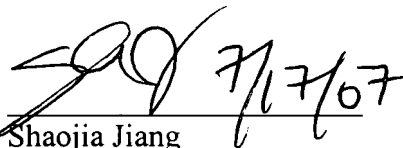
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GK


Shaojia Jiang
Supervisory Patent Examiner
Art Unit 1623